

AMENDMENTS TO THE DRAWINGS

Formal drawings are enclosed replacing sheets 1-5 as filed. Also, Figs. 14, 18A and 18B have corrections to reference numbers as described in the remarks below. The insert of Fig. 14 has now been labeled Fig. 14A. Marked up and clean sheets are enclosed for the sheets with Figs. 14, 18A and 18B with the marked up sheets immediately after this page and clean sheets at the end of the Amendment.

Attachment: Replacement Sheets 1-5

### REMARKS

Claims 1-15, 17-24 are pending. By this Amendment, claims 1 and 12 are amended to more particularly point out Applicants' claimed invention. Claim 16 has been canceled without prejudice. Claim 1 has been amended for clarity, and Applicants do not intend to narrow claim 1. Claim 12 has been amended to provide antecedent basis for features of the dependent claims. The amendment of claim 12 is supported by the specification, for example, at page 12, lines 1-14. Applicants have canceled claim 16 in view of a typographical error in the claim and corresponding text of the application. Applicants note for the record that the dimensions for the screw length should have read 4 mm to 10 cm, and a person of ordinary skill in the art would have recognized the error in dimensions based on the remaining portions of the description and the Figures incorporated from the parent provisional, such as slides 18 and 21 of the parent Provisional Appendix. Also, the specification has been amended to correct the brief description of the drawings to be consistent with the detailed description of these drawings and to correct typographical errors. No new matter is introduced by the amendments.

The drawings have been corrected to address issues raised by the Examiner. Corrected drawings and, where appropriate, marked up drawings are enclosed. These revisions are discussed further below.

### Drawings

Applicants thank the Examiner for a careful review of the Figures. Applicants provide the following response to the issues raised by the Examiner.

The Examiner noted that Figs. 9 and 14 had inserts that were not properly identified. However, only the view in the insert of Fig. 14 is a modified view. Thus, this insert has been labeled Fig. 14A. The insert of Fig. 9 depicts an expanded view. This has now been properly recited in the brief description of the drawings. Since the insert of Fig. 9 is not a modified view, Applicants respectfully believe that a separate figure number is not needed or suitable for this insert.

The Examiner noted that the reference numbers 260 and 316 were omitted from the figures. These have been added to correspond with the description in the text. No new matter is introduced.

The Examiner further objected to the drawings for being informal. Formal drawings are enclosed.

In view of the corrected drawings enclosed and the above comments, Applicants respectfully request withdrawal of the objection to the drawings.

#### Specification

The Examiner objected to the specification for inconsistent terminology. In particular, the Examiner objected to the use of reference number 130 on pages 7 and 11. Applicants thank the Examiner for a careful reading of the specification. Applicants have moved the reference number on page 7 for consistency. As amended, the reference number is used consistently. In view of the correction, Applicants respectfully request withdrawal of the objection to the specification.

#### Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 1-11 and 12-20 under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, the Examiner noted particular recitation of elements without proper antecedent reference in claims 1, 12, 18 and 19. Applicants thank the Examiner for a careful reading of the claims.

In claim 1, the Examiner noted a lack of antecedent basis for "the sacroiliac joint." Applicants have replace "the" with "a".

In claim 12, the Examiner noted a lack of antecedent basis for "the immobilization." Applicants have deleted "the".

In claims 18 and 19, the Examiner noted, respectively, the lack of antecedent basis for "the tip" and "the threads". Applicants have amended claim 12 to provide the proper antecedent basis for claims 18 and 19.

In view of the above noted amendments, the claims should presently be definite. Applicants respectfully request withdrawal of the rejections of claims 1-11 and 12-20 under 35 U.S.C. § 112, second paragraph as being indefinite.

#### Rejections Over Kambin

The Examiner rejected claims 1-5 and 8-11 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,175,758 to Kambin (the Kambin patent). The Examiner asserts that Kambin teaches all of the elements of Applicants' claimed invention. Evidently, some of these features are asserted to be inherent since they are not explicitly recited in the Kambin patent. Applicants maintain that the Kambin patent does not render Applicants' claimed invention *prima facie* anticipated. Applicants respectfully request reconsideration of the rejection based on the following comments.

"If the prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is 'inherent' in its disclosure. To establish inherency, the intrinsic evidence 'must make it clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Robertson, 49 USPQ2d 1949, 1950, 1951 (Fed. Cir. 1999), citing Continental Can Co. v. Monsanto Co., 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

"Every element of the claimed invention must be literally present, arranged as in the claim. **The identical invention must be shown in as complete detail as is contained in the patent claim.**" Richardson v. U.S. Suzuki Motor Corp., 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)(Internal citations omitted, and emphasis added.); see also MPEP 2131. "Here, as well,

anticipation is **not** shown by a prior art disclosure which is only '**substantially the same**' as the claimed invention." Jamesbury Corp. v. Litton Industrial Products, Inc., 225 USPQ 253, 256 (Fed. Cir. 1985)(emphasis added).

With respect to the "taper of at least one degree" and the "dimension suitable for insertion into the sacroiliac joint of a human patient," the Examiner points to Figs. 6 and 8 of the Kambin patent. Merriam-Webster's Collegiate Dictionary - Tenth Edition defines a taper as "a gradual diminution of thickness, diameter, or width in an elongated object. Applicants do not see any taper in Figs. 6 or 8. Similarly, no dimensions can be gleaned from these figures. The Kambin patent is directed to devices to fuse vertebrae, not a human sacroiliac joint. Therefore, the Kambin patent clearly does not teach the "dimension suitable for insertion into the sacroiliac joint of a human patient." These two features of Applicants' claimed invention are clearly not inherently disclosed based on the teachings of the Kambin patent. Other claimed features are similarly not inherently or explicitly disclosed. Based on the arguments already presented, further discussion of these details would be unnecessary.

Since the Kambin patent does not explicitly or inherently teach all of the features of Applicants' claimed invention, Applicants respectfully request withdrawal of the rejection of claims 1-5 and 8-11 under 35 U.S.C. § 102(b) as being anticipated by the Kambin patent.

#### Rejection Over Bowman et al.

The Examiner rejected claims 12-24 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,950,270 to Bowman et al. (the Bowman patent). Again, with respect to the relevant claims, the Examiner asserted that the Bowman patent teaches all of the claim elements. With all due respect, the Bowman patent falls far short of establishing *prima facie* anticipation. Applicants respectfully request reconsideration of the rejections based on the following comments, which are separated for each independent claim. The legal standards for inherent anticipation are summarized above.

Claims 11-20

The Examiner points to Figs. 1 and 2 of the Bowman patent for teaching "a taper of at least one degree" and "a dimension suitable for insertion into the sacroiliac joint of a human patient." With all due respect, neither of these features is taught in the Bowman patent. For clarity, Applicants have indicated that the taper is associated with the shaft of the screw, as previously implied from the specification. Since the Bowman patent does not explicitly or inherently teach all of the claim features, the Bowman patent does not *prima facie* anticipate Applicants claimed invention.

Claims 21-24

With all due respect, the Bowman patent does not seem to teach or suggest anything whatsoever about the sacroiliac joint or its immobilization. Therefore, the Bowman patent falls far, far short of rendering these claims *prima facie* anticipated.

Summary

Since the Bowman patent does not teach or suggest explicitly or inherently all of the elements of Applicants' claimed invention, Applicants respectfully request withdrawal of the rejection of claims 12-24 under 35 U.S.C. § 102(b) as being anticipated by the Bowman patent.

Rejection of Claims 15-17

The Examiner rejected claims 15-17 under 35 U.S.C. § 103(a) as being unpatentable over the Bowman patent. The Examiner asserted that the Bowman patent taught all of the features of the claims except for the degree of taper, the length of the screw and the widest thickness. With all due respect, the Examiner has fallen clearly short of establishing *prima facie* obviousness. Applicants respectfully request reconsideration of the rejection based on the following comments.

Prima facie obviousness is not established if all the elements of the rejected claim are not disclosed or suggested in the cited art. In re Ochiai, 37 USPQ 1127, 1131 (Fed. Cir. 1995). ("The test for obviousness *vel non* is statutory. It requires that one compare the claim's 'subject

matter as a whole' with the prior art 'to which said subject matter pertains.'"). See also, MPEP 2143.03 "All Claim Limitations Must Be Taught or Suggested," citing In re Royka, 180 USPQ 580 (CCPA 1974). "To establish prima facie obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art." MPEP 2143.03.

Claims 15-17 depend from claim 12. The deficiencies of the Bowman patent with respect to claim 12 are described above. Specifically, the Bowman patent does not teach or suggest a taper of any kind or "a dimension suitable for insertion into the sacroiliac joint of a human patient." While the Examiner indicated that the claimed dimensions are a matter choice, there is no basis for such an assertion when the objectives implied by the claim language and the objectives taught in the reference are not the same. Since the Bowman patent does not teach immobilizing the sacroiliac joint, there is no basis for designing the claimed features. Since Bowman patent does not teach or suggest all of the features of Applicants' claimed invention, the Bowman patent clearly does not render claims 15-17 *prima facie* obvious. Applicants respectfully request withdrawal of the rejection of claims 15-17 under 35 U.S.C. § 103(a) as being unpatentable over the Bowman patent.

#### Rejections of Claims 6 and 7

The Examiner rejected claims 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over the Kambin patent in view of the Bowman patent. The Examiner asserts that Kambin teaches Applicants' claimed invention except for the presence of a biologically active agent. The Examiner further asserts that the Bowman patent teaches biologically active agents. With all due respect, neither of these assertions is on point. The combined teachings of the Kambin patent and the Bowman patent clearly do not render Applicants' claimed invention *prima facie* obvious. Applicants respectfully request reconsideration of the rejection based on the following comments.

First, claims 6 and 7 depend from claim 1. The deficiencies of the Kambin patent with respect to claim 1 are discussed in detail above. Specifically, the Kambin patent does not

teach or suggest a "dimension suitable for insertion into the sacroiliac joint of a human patient." Furthermore, the Examiner seems to be equating biocompatible with bioactive. With all due respect, this is an error, and the Bowman patent does not teach or suggest bioactive agents. Biocompatible is a term of art that means nontoxic and nonharmful within a patient. On the other hand, bioactive implies an active or functional role. As noted in Applicants' specification, for example, at page 14, lines 28-31, bioactive agents can be drugs, hormones or the like.

Since the cited references do not teach or suggest all of the features of claim 1 or a bioactive agent, the combined teachings of the Kambin patent and the Bowman patent do not render claims 6 and 7 *prima facie* obvious. Applicants respectfully request withdrawal of the rejection of claims 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over the Kambin patent in view of the Bowman patent.

#### Rejection of Claim 24

The Examiner rejected claim 24 under 35 U.S.C. § 103(a) as being unpatentable over the Bowman patent in view of the Kambin patent. The Examiner asserts that Bowman discloses the claimed invention except for the use of imaging. The Examiner cited the Kambin patent for the disclosure of imaging. With all due respect, both of these assertions fall short. The cited references simply do not render Applicants' claimed invention *prima facie* obvious. Applicants respectfully request reconsideration of the rejection based on the following comments.

Neither the Bowman patent nor the Kambin patent teach, suggest or motivate anything related in any way to immobilization of the Sacroiliac joint. The teachings of these references simply cannot and do not render obvious a method for immobilizing the sacroiliac joint. Furthermore, while the Kambin patent teaches visualization, the Kambin patent does **not** teach or suggest **real time imaging**. In contrast, the Kambin patent teaches drawing lines on the patient's back for placement of devices based on prior (**not real time**) imaging, e.g., a CT scan. See, column 3, lines 1-10. Since the teachings of the references fall far, far short of disclosing,



suggesting or motivating the claimed invention, the cited references very clearly do not render Applicants' claimed invention *prima facie* obvious.

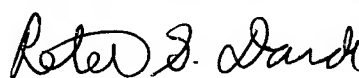
Due to the clear deficiencies of the references, Applicants respectfully request withdrawal of the rejection of claim 24 under 35 U.S.C. § 103(a) as being unpatentable over the Bowman patent in view of the Kambin patent.

### CONCLUSIONS

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Peter S. Dardi". The signature is fluid and cursive, with the first name "Peter" and last name "Dardi" clearly distinguishable.

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Fig. 11

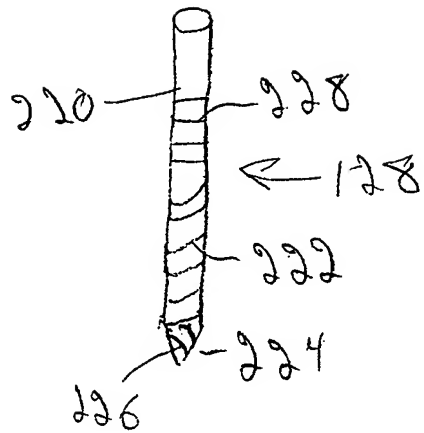


Fig. 12

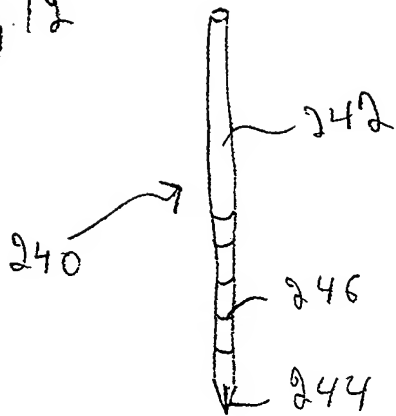


Fig. 13

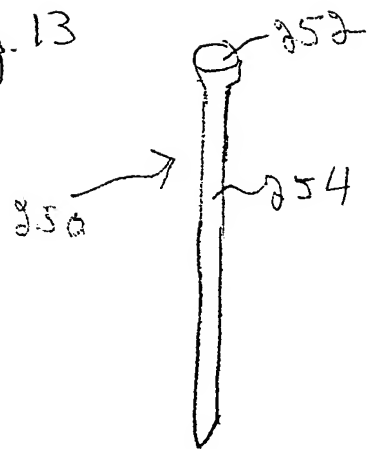


Fig. 14

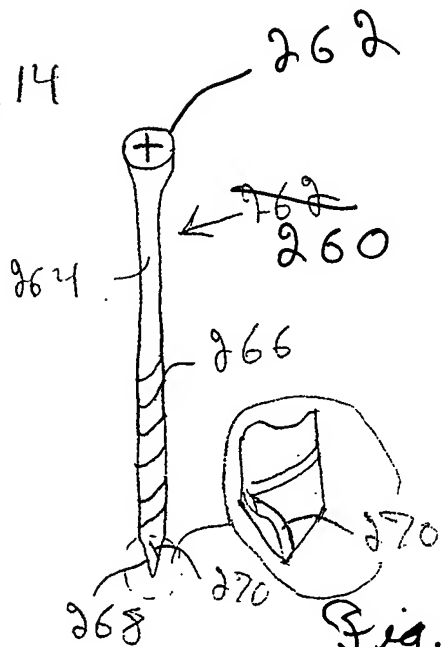


Fig. 15

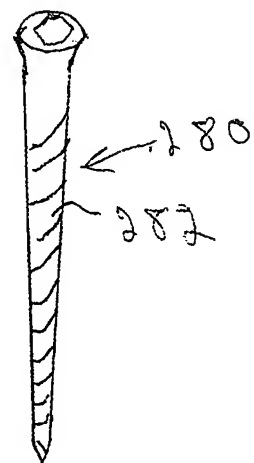


Fig. 14A

Fig. 16A

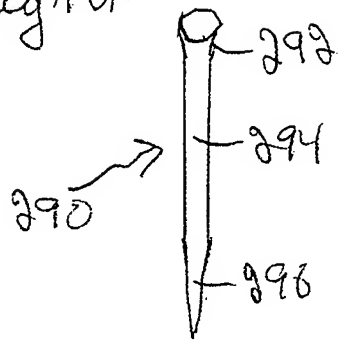


Fig. 16B

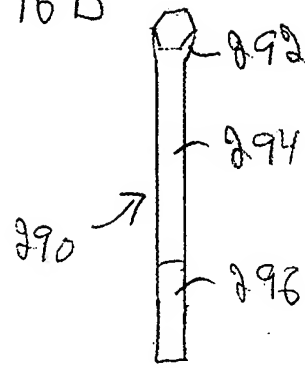


Fig. 17A

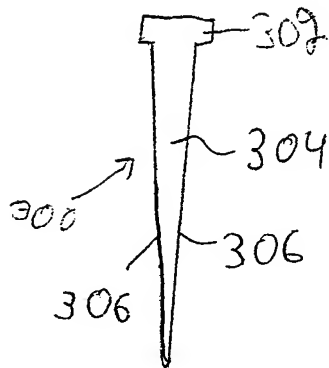


Fig. 17B

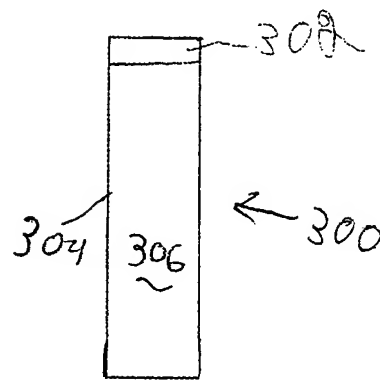


Fig. 18A

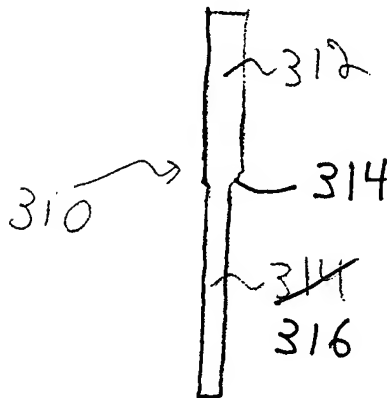


Fig. 18B

